



Original article

A pilot study evaluating the effect of early physical therapy on pain and disabilities after breast cancer surgery: Prospective randomized control trail



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ABSTRACT

Background: Morbidity of the shoulders after breast cancer (BC) surgery is a common side effect that includes; persistent pain, function limitation, and decreased range of motion (ROM). This study examines the effect of early physical therapy (PT) and patient's education on these morbidities.

Methods: A prospective, randomized clinical trial was conducted at a single medical center from October 2018 until April 2019. Women scheduled for breast cancer surgery were divided into intervention or control as standard care. The intervention included a PT treatment that included exercise instructions from the first postoperative day. Pain levels, upper limb function, ROM, and complications were measured.

Results: The study includes 157 women (mean age, 52.2 ± 12.9). Early PT reduced pain levels at the first month (NPRS 1.5 ± 1.2) and six months (NPRS 0.5 ± 0.8), compared with control (NPRS 2.1 ± 1.4 , 1.0 ± 1.2), $p = 0.019$ and $p = 0.011$, respectively. Subdivision of the sample into small and extensive surgeries revealed additional positive effect for the intervention six months postoperatively on functional disabilities, $p = 0.004$ and $p = 0.032$ respectively. No complications attributable to the intervention were recorded.

Conclusions: Early PT and patient education reduces pain levels, and may improve function disabilities, without causing postoperative complications, although a larger study is needed to achieve unequivocal results.

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1. Introduction

Breast cancer (BC) is the most frequent malignancy among women worldwide [1]. Surgery is a central component of primary BC management, and axillary surgery is often necessary [2]. Breast cancer surgeries can cause a variety of adverse effects, ranging from restriction in function and range of motion (ROM) to emotional difficulties [3]. Persistent pain is reported by 20–68 % of patients, especially after axillary lymph node dissection (ALND), with additional risk factors including young age, the severity of acute

postoperative pain, chemotherapy, and radiation [4]. Functional disability and decreased ROM are common side effects after BC surgery and treatments, reported by 10–60 % of patients, and may last for years after recovery [5]. Long-term shoulder impairments are most often caused by lymph node dissection, mastectomy procedure, positive nodes, and older age [6].

Shoulder morbidity is a major factor in the need for multiple sick days and delayed return to work [7], reduced daily activities, and poorer quality of life [8].

Physical therapy (PT) can help to reduce pain, fatigue, and symptoms of oncologic treatments and promote quality of life [9], physical functioning and ROM, throughout the recovery process [10,11]. Pain education and exercise have been suggested as effective in reducing postoperative pain [12,13]. Although there is

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evidence regarding the effectiveness of early PT [14], surgeons still refrain from referring to PT as it may lead to increased bleeding, seroma (fluid accumulation in the tissue) [15], and lymphedema (chronic edema) [16,17]. It is arising the discussion when it is the right time to start PT and exercises [18,19].

The objective of this study is to verify the influence of early rehabilitative exercise on function disabilities, pain and ROM, and postoperative complications in women who undergo BC surgery.

2. Material and methods

This study was prospective, randomized, conducted in a single medical center between October 01, 2018 and April 30, 2019. The Institutional Review Board approved the trial (approval number: 0122-17 Helsinki Board Assuta Medical Center) and registered on the National Institutes of Health's on August 11, 2020 (ClinicalTrials.gov; study identifier NCT03389204) URL: <https://clinicaltrials.gov/ct2/show/NCT03389204>.

All patients provided written informed consent before enrollment to participated in the study.

Patients: Study patients were women aged 18–85, functionally independent, who were diagnosed with BC and were referred for oncology surgery.

Exclusion criteria were cognitive disorders, fibromyalgia or chronic pain disorders, neurological disorders causing permanent disability, previous breast surgery, lymphedema before the surgery, previous shoulder surgery, or injuries causing limited ROM (using DrGoniometer application), back and spinal morbidity. Renal failure, ischemic heart disease radical mastectomies, latissimus dorsi, and flap reconstructions.

Randomization and blinding: A single investigator randomly assigned all patients before surgery to an intervention or control group using sealed envelopes.

The sample was divided postoperatively by type of surgery into two groups; small and extensive surgeries in order to obtain information on the impact of the extent of surgery.

Small surgeries included lumpectomy and axillary surgery, and extensive surgeries included mastectomy and axillary surgery, with or without reconstruction. The groups were then analyzed according to the randomization to the intervention or control. Resulting in four subgroups; small surgeries with intervention (A) and control (B), extensive surgeries with intervention (C), and control (D).

The study was conducted without blindness. Patients were operated by eighteen different surgeons and plastic surgeons working in the hospital. The intervention was given by six physical therapists, who were trained to give uniform instructions, both verbally and by demonstrating the exercises. Data collection and evaluations were done by a single investigator.

Study procedures and intervention: Upon admission for surgery, the participants signed an informed consent form, performed a preoperative assessment of the exclusion criteria and outcome measures. On the day after the surgery, patients in the intervention group received PT treatment that included therapeutic exercises and instructions for home exercise in the form of a booklet, with the aim of restoring the full ROM of the upper limbs. The recommendations were to perform the exercises three times a day, five repetitions of each exercise until maximum function and ROM are restored without pain. In addition to the exercises, the patients' received patient education regarding pain control strategies, daily functioning, and when to seek PT. Patients with axillary drains were instructed to limit movement of the shoulders to 90°, while patients without drainage were instructed to gradually complete the therapeutic exercises until full ROM was achieved, avoiding pain or discomfort. When the ROM was full, the patients were instructed

for additional exercises that included stretching and strength exercises. One week and a month after the surgery, phone calls were initiated to check how all the participants were doing, and the intervention group were asked about the difficulty in performing the exercises. Nonetheless, compliance with the protocol was not examined quantitatively. All the participants were explained about limb edema, limitation in ROM, pain and appearance of a thread or tendon in the armpit. If these conditions appeared, they were instructed to update the researcher, and they were referred for lymphatic physical therapy evaluation.

The control group did not received orientation to perform exercises and PT. Our hospital is a private institution, the current practice is that each surgeon decides whether to give a referral to PT during hospitalization, so in practice there are patients who receive treatment and those who do not. Patients in the control group received guidance of a BC nurse during hospitalization, regarding pain, wound care, and instructions; in case of pain, edema, decreased function or movement for more than three weeks, to consult the doctor.

Outcome measures: Pain was evaluated using Numeric Pain Rating Scale (NPRS) [20], pain levels were rated from 0 (no pain) to 10 (worst pain). Pain severity was ranked as mild (NPRS 1–2), moderate (NPRS 3–5) and severe (NPRS 6–10). The Disabilities of Arm, Shoulder & Hand questionnaire (QuickDASH) [21] was used for assessing the physical function of the upper limbs. The questionnaire includes 11 items evaluating different function aspects, each item has five response options, the scale scores are ranging from 0 (no disability) to 100 (most severe disability). Flexion and abduction ROM were evaluated in degrees using DrGoniometer application [22]. Outcome measures were evaluated preoperatively and one, 3, and 6 months postoperatively. Due to geographical distance, lymphedema and the presence of axillar web syndrome (AWS) were reported by the participants (evaluated additionally by a lymphatic specialist). During the hospitalization (perioperatively) pain values, number of hospital days, amount of drain fluids (average cc per day from all drains), and complications were recorded. The patients reported long-term complications at each follow-up period.

Statistical Analysis: To calculate sample size estimation, the PS Power and Sample Size Calculations software (Version 3.0, January 2009) was used. QuickDASH instrument was the main outcome measure used to evaluated shoulder functional disability. QuickDASH score after BC surgery [23] (43.2 ± 18) were compared with the general population [24] (10.1 ± 14.6) to estimate the sample size. Using this data and the probability of type I error was 0.05, and the probability of type II error was 0.2, 30 experimental subjects and 30 control subjects were needed to reject the null hypothesis. Since four different sub-groups were evaluated, with probability of up to 20 % dropping out of the study, 160 patients were planned to enter the study.

Statistical analysis was performed using the SPSS statistical package, Version 21 (SPSS Inc, Chicago, IL, USA). The significance level was set at $p < 0.05$. The T-test was used to compare normally distributed parameters. The non-parametric Mann-Whitney rank-sum test for independent samples and Kruskal Wallis for several independent variables were applied for the testing difference between continuous parameters. Nominal variables were evaluated by the chi-squared test.

Data Availability: Data available on request from the authors.

3. Results

A total of 188 patients were recruited to the study (Fig. 1). Excluded patients add up to 28 (14.89 %): one (3.6 %) had a non-malignant tumor, 17 women (60.7 %) had previous breast surgery,

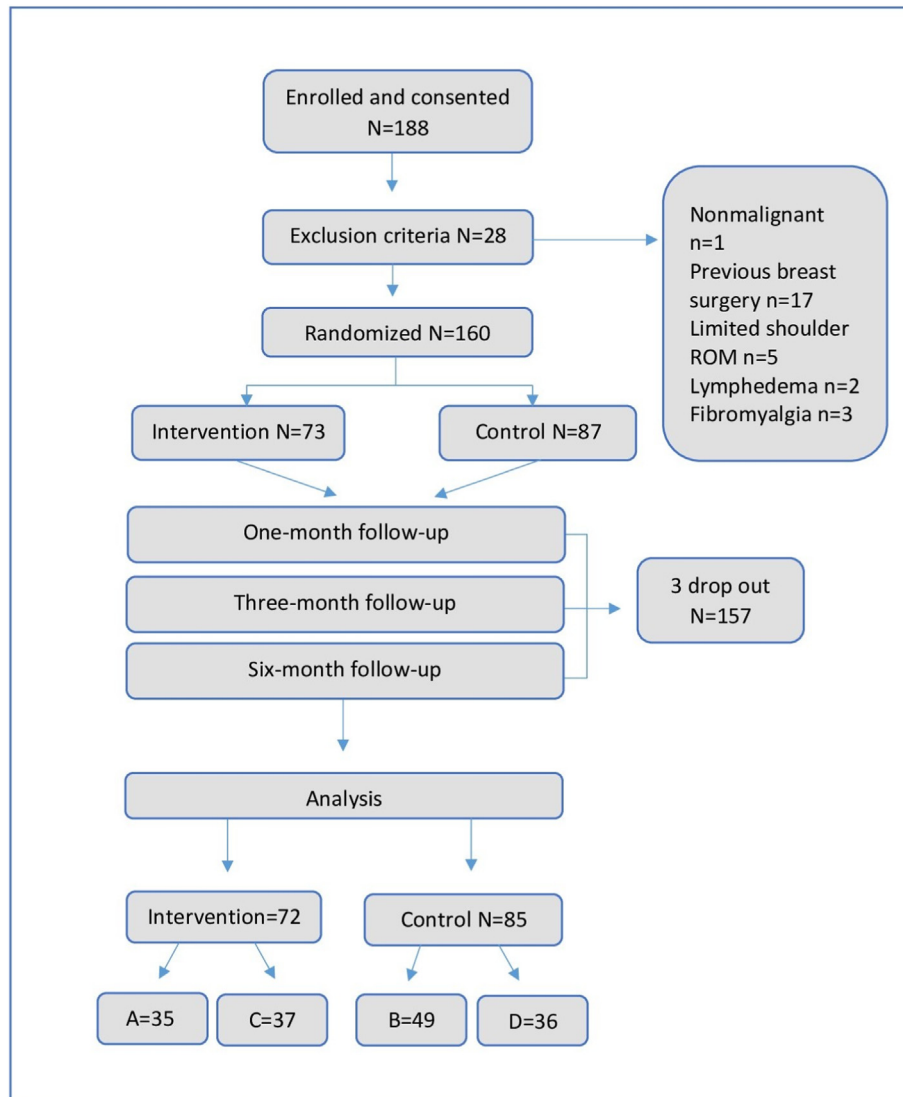


Fig. 1. Flow chart of the study. A: Small surgery with intervention, B: Small surgery control, C: Extensive surgery with intervention, D: Extensive surgery control.

five (17.9 %) had limited shoulder ROM mostly rotator cuff tears, two (7.1 %) had lymphedema, and three (11 %) had fibromyalgia. Of 160 remaining patients, three did not complete the follow-up. The remnant 157 patients entered for the study data analysis, 72 in the intervention and 85 in the control group.

3.1. Baseline characteristics

The patient's mean age was 52.2 ± 12.9 years, with body mass index (BMI) of 25.7 ± 4.4 kg/m². Average age, BMI, duration of hospitalization, and amount of discharge in the drains were similar among study groups (Table 1).

In the baseline characteristics, difference was found between two groups; there were more lumpectomy surgeries in the control group 15 (17.6 %) compared to the intervention group, which had only four (5.6 %) $p = 0.020$.

Oncology treatments included adjuvant 60 (38 %) and neo-adjuvant chemotherapy 35 (22.3 %), three-dimensional conformal radiation therapy 96 (61.1 %), and intraoperative radiation therapy 12 (7.7 %). More participating in the intervention group received radiation therapy (70.8 %) compare to the control group (52.9 %),

$p = 0.022$. There were no differences between the groups in the amount of adjuvant chemotherapy and adjuvant therapy treatments.

Moreover, the number of participants who received post-hospital PT treatments due to pain, limitation of movement, function, AWS, or lymphedema were also examined to reduce bias 16 (22.2 %) compared with control 14 (16.5 %), with no differences between groups, $p = 0.361$.

3.2. Postoperative complications

Between the short-term complications, which occurred during the hospitalization, seven (4.4 %) participants bled after surgery, with four of them needed revision surgery, all occurred before PT treatments. In the intervention group, a single patient (1.4 %) had hematoma compare to five (5.9 %) in the control group ($p = 0.143$). In the Long-term complications, two patients that received intervention had seromas (2.8 %) compared with nine (10.6 %) in the control group ($p = 0.056$). In addition, 17 patients in each group develop AWS or lymphedema, without significant differences between groups (Table 2).

Table 1
Baseline characteristics.

Variables	Intervention N = 72	Control N = 85	P value
Age (years)	53.3 ± 12.7	51.2 ± 13.1	0.441
BMI (kg/m ²)	25.0 ± 4.7	25.0 ± 4.7	0.771
H. stay (days)	1.6 ± 0.8	1.6 ± 0.8	0.936
Drainage (cc per day)	20.3 ± 34.7	20.3 ± 34.7	0.909
<i>Cancer stage N. (%)</i>			
0/prophylactic	12 (16.7)	35 (41.2)	0.447
1 A	40 (55.6)	34 (40.0)	
1 B	2 (2.8)	5 (5.9)	
2 A	12 (16.7)	7 (8.2)	
2 B	4 (5.6)	2 (2.4)	
3 A	0	1 (1.2)	
3C	1 (1.4)	0	
4	1 (1.4)	1 (1.2)	
<i>Type of surgery N. (%)</i>			
<i>Small surgeries</i>			
Lumpectomy	4 (5.6)	15 (17.6)	0.020*
Lumpectomy + SLNB	23 (31.9)	16 (18.8)	0.081
Lumpectomy + ALND	7 (9.7)	0	–
<i>Extensive surgeries</i>			
Partial/modified mastectomy + SLNB	14 (19.4)	21 (24.7)	0.429
Partial/modified mastectomy + ALND	1 (1.4)	4 (4.7)	0.238
Partial/modified/bilateral mastectomy + reconstruction	23 (31.9)	29 (34.1)	0.773
<i>Type of reconstruction N. (%)</i>			
Oncoplastic/BCT	5 (20.8)	7 (22.6)	0.761
Implant base definitive	16 (66.7)	23 (74.2)	0.874
Implant base expender	3 (12.5)	1 (3.2)	0.236
<i>Onc. Treatments N. (%)</i>			
Neoadjuvant	17 (23.6)	18 (21.1)	0.715
Adjuvant	33 (45.8)	27 (31.8)	0.071
Radiation	51 (70.8)	45 (52.9)	0.022*
IORT	8 (11.1)	4 (4.7)	0.145
<i>Additional factors N. (%)</i>			
BRCA gene carrier	10 (13.9)	16 (18.8)	0.409
Physical therapy	16 (22.2)	14 (16.5)	0.361

Categorical variables are presented as number (N) and percentage (%), and continuous variables are presented as mean ± standard deviation. *Significant p-value (<0.05). **Abbreviations:** BMI: Body Mass Index, H: Hospital, **Cancer stage:** Using the TNM staging system, **SLNB:** Sentinel Lymph Node Biopsy, **ALND:** Axillary Lymph Node Dissection, **Onc:** Oncologic, **Oncoplastic/BCT:** Breast surgery without implants/Breast Conserving Therapy. **Radiation:** Three-dimensional Conformal Radiotherapy, **IORT:** Intraoperative radiation therapy, **BRCA gene carrier:** Who underwent preventive surgery, **Physical therapy:** The number of patients needed physical therapy after discharge subsequent to pain, functional limitation, decreased range of motion, lymphedema or AWS.

3.3. The effect of physical therapy on function, pain and ROM

3.3.1. Functional disabilities

One-month postoperative functional disabilities were reported by 126 patients (85.7 %) with a mean QuickDASH score of 19.2 ± 17.0. Six months postoperative 70 patients (44.6 %) reported

Table 2
Postoperative complications.

Complication	Intervention N = 72		Control N = 85	
	N (%)		N (%)	p value
<i>Short term</i>				
Hematoma	1 (1.4)		5 (5.9)	0.143
Bleeding	4 (5.6)		3 (3.5)	0.540
Revision Surgery	1 (1.4)		3 (3.5)	0.396
<i>Long term</i>				
Seroma	2 (2.8)		9 (10.6)	0.056
Infection	6 (8.3)		5 (5.9)	0.549
Lymphedema (6 MTH)	9 (13.0)		6 (7.8)	0.297
AWS (3 MTH)	8 (11.4)		11 (12.9 %)	0.806

Short-term complications occurred during hospitalization, and long-term complications occurred after discharge.

Abbreviations: N: Number, %: Percent, **MTH:** Months, **AWS:** Axillar Web Syndrome. *p ≤ 0.05 significant.

disability with a mean QuickDASH score of 4.8 ± 8.4. The intervention did not affect disability values throughout the study (reported in Table 3).

3.3.2. Pain

One month postoperatively 44 patients (28.5 %) reported having no pain, 65 (41.1 %) reported mild pain, and 48 (30.4 %) reported moderate pain, severe pain was not reported, and mean pain score was relatively low (NPRS 1.8 ± 1.3). Six months after surgery 93 (59.5 %) reported having no pain, 48 (30.4 %) reported mild pain (NPRS 1.4), and only 16 patients (10.1 %) reported moderate pain (NPRS 3.5), with a mean score of 0.7 ± 1.0.

The intervention significantly reduced pain values during the first month (NPRS 1.5 ± 1.2), compared with control (NPRS 2.1 ± 1.4), p = 0.019, and at six months (NPRS 0.5 ± 0.8), compared with control (NPRS 1.0 ± 1.2), p = 0.011.

3.3.3. Flexion and abduction ROM

The intervention did not improve the participants' flexion and abduction ROM relative to the control throughout the follow-up period.

Table 3
The effect of postoperative hospital physical therapy on functional disability scores, pain levels and range of motion.

Time of follow-up	Small surgeries			Extensive surgeries			All		
	AN = 35	BN = 37	P value	CN = 49	DN = 36	P value	Treatment	Control	P value
<i>Functional disabilities by QuickDASH</i>									
Pre-op	2.4 ± 4.2	4.2 ± 6.8	0.160	4.1 ± 7.1	3.8 ± 8.2	0.827	3.0 ± 6.0	4.1 ± 7.5	0.380
1 month	4.2 ± 6.8	15.5 ± 14.7	0.183	20.8 ± 14.7	30.3 ± 18.2	0.021*	16.4 ± 15.8	21.7 ± 17.8	0.056
3 months	3.4 ± 5.3	8.5 ± 12.6	0.010*	9.7 ± 9.0	13.1 ± 14.6	0.232	6.7 ± 8.4	10.1 ± 13.4	0.268
6 months	1.1 ± 2.0	5.0 ± 7.0	0.004*	5.0 ± 7.0	10.0 ± 12.0	0.032*	3.1 ± 5.6	6.3 ± 8.4	0.210
<i>Pain by NPRS</i>									
Pre-op	1.2 ± 1.2	1.5 ± 1.2	0.560	1.7 ± 1.2	2.7 ± 1.3	0.724	0.2 ± 0.7	0.2 ± 0.7	0.833
1 month	1.2 ± 1.2	1.65 ± 1.2	0.236	1.74 ± 1.2	2.6 ± 1.2	0.003*	1.5 ± 1.2	2.1 ± 1.4	0.019*
3 months	0.6 ± 0.9	1.1 ± 1.1	0.034*	1.5 ± 1.1	1.69 ± 1.3	0.642	1.0 ± 1.1	1.3 ± 1.2	0.166
6 months	0.2 ± 0.5	0.7 ± 1.0	0.009*	0.8 ± 1.0	1.3 ± 1.3	0.094	0.5 ± 0.8	1.0 ± 1.2	0.011*
<i>Shoulder flexion ROM</i>									
Pre-op	160 ± 9	163 ± 10	0.186	158 ± 10	158 ± 7	0.988	157.2 ± 10.2	159.6 ± 9.2	0.131
1 month	145 ± 22	144 ± 23	0.764	144 ± 23	135 ± 26	0.124	143.0 ± 28.9	144.3 ± 23.4	0.869
3 months	154 ± 14	143 ± 24	0.364	157 ± 16	143 ± 24	0.014*	155.3 ± 14.4	146.4 ± 24.7	0.064
6 months	162 ± 7	162 ± 10	0.496	155 ± 16	147 ± 25	0.054	156.3 ± 12.8	152.2 ± 19.0	0.298
<i>Shoulder abduction ROM</i>									
Pre-op	159 ± 10	162 ± 9	0.207	161 ± 9	161 ± 7	0.936	160.6 ± 9.8	162.6 ± 8.6	0.277
1 month	147 ± 20	151 ± 19	0.385	146 ± 21	132 ± 28	0.019*	146.9 ± 20.8	143.1 ± 25.4	0.475
3 months	155 ± 12	150 ± 24	0.563	156 ± 14	146 ± 25	0.057	156.0 ± 13.6	149.1 ± 24.7	0.332
6 months	161 ± 6	160 ± 12	0.144	156 ± 20	149 ± 29	0.134	157.5 ± 13.8	155.7 ± 17.5	0.716

A: Small surgery with intervention, B: Small surgery control, C: Extensive surgery with intervention, D: Extensive surgery control. All variables are presented as mean ± standard deviation. *Significant p-value (<0.05).

Abbreviations: N: Number, **Pre-op:** Preoperative, **QuickDASH:** Quick form of Disabilities of the Arm, Shoulder and Hand questionnaire, **NPRS:** Numeric Pain Rating Scale, **ROM:** Range Of Motion.

3.3.4. The effect of radiation

Patients underwent three-dimensional conformal radiation therapy which induce 16–25 fraction between 4 and 6 weeks after surgery (if adjuvant chemotherapy was not needed). Radiotherapy negatively affected the shoulder flexion ROM six months postoperatively (150.6 ± 19.4), relative to women who did not receive radiation (158.1 ± 11.9), $p = 0.010$. No other affect was observed due to radiation therapy, on functional limitation ($p = 0.063$), pain levels (0.333) or shoulder abduction ROM ($p = 0.142$).

The effect of physical therapy divided into small and extensive surgeries:

Functional disabilities according to the extent of the surgery:

One-month postoperative, shoulder and arm functional limitation were reported by 66 (76.9 %) of patients after small surgeries (QuickDASH 25.5 ± 17.1), and by 66 (95.7 %) of patients after extensive surgeries (QuickDASH 13.6 ± 15.0), $p < 0.001$. After six months, 44 (60.3 %) patients reported function disabilities after small surgeries (QuickDASH 3.0 ± 6.1), in comparison with 26 (31 %) (QuickDASH 6.9 ± 10.1) patients after extensive surgeries, $p < 0.001$.

In the small surgeries, the intervention improved shoulder disability scores for group A (QuickDASH 3.4) compared to group B (QuickDASH 8.5) at three months, with a significance level of $p = 0.010$. The effect lasted six months postoperatively comparing group A (QuickDASH 1.1 ± 2.0) and group B (QuickDASH 5.0 ± 7.0), $p = 0.004$, shown Fig. 2.

In the extensive surgery groups, PT reduced disability levels at one month postoperatively for group C (QuickDASH 20.8 ± 14.7) compared to D (QuickDASH 30.3 ± 18.2), $p = 0.021$, and at six months in group C (QuickDASH 5.0) compared to D (QuickDASH 10.0) $p = 0.032$. No further significant differences were found.

3.3.5. Pain according to the extent of the surgery

Higher pain levels were reported six months postoperatively in the extensive surgery group (NPRS 1.8 ± 1.3) compared to the small surgery group (NPRS 0.7 ± 1.0), $p = 0.002$. Similar differences were found at the first ($p = 0.001$) and second ($p = 0.001$) follow-ups.

In the small surgeries group, the intervention group had lower pain values at three months postoperatively, in group A (NPRS

0.6 ± 0.9) compared with group B (NPRS 1.1 ± 1.1), $p = 0.034$, and at six months as group A (NPRS 0.2 ± 0.5) relative to group B (NPRS 0.7 ± 1.0, $p = 0.009$), demonstrated at Fig. 3.

In extensive surgeries, the positive effect of the intervention was notable only at the first month, as group C reported lower levels of pain (1.7 ± 1.2) than group D (2.6 ± 1.2), $p = 0.003$.

3.3.6. ROM according to the extent of the surgery

In the small surgeries, the flexion and extension ROM were not affected at all by the intervention. In the extensive surgeries, the flexion ROM improved three months postoperative after the intervention (157 ± 16°) relative to the control group (143 ± 24°), $p = 0.014$. In addition, an improvement in the extension ROM was observed one month postoperatively in participants who received the intervention (146 ± 21°) in relation to the control (132 ± 28°), $p = 0.019$.

4. Discussion

Our private hospital treats approximately 1500 BC patients a year. The purpose of this study was to understand more about the role of the hospital PT as a small part of the long process BC patient undergo, and to reduce surgeons concerns of referring to PT during hospitalization, especially after extensive surgeries like mastectomy with prosthesis. The concerns come from past studies, that have found that early start of exercise after breast surgery can cause more bleeding and seroma [10,15]. In contrast, postponing or avoiding exercises may adversely affect shoulder function and ROM [6,26].

Therefore, the practice in our hospital is that each surgeon decides the approach to post-surgical PT treatments, consequences there are patients who receive PT and those who do not, hence the question of research. Consequently, all participants were monitored for complications, and if any postoperative symptoms appeared, participants were referred for individual PT evaluation and treatment.

The results are consistent with past studies and show that shoulder pain and disability are common side effects of BC surgery,

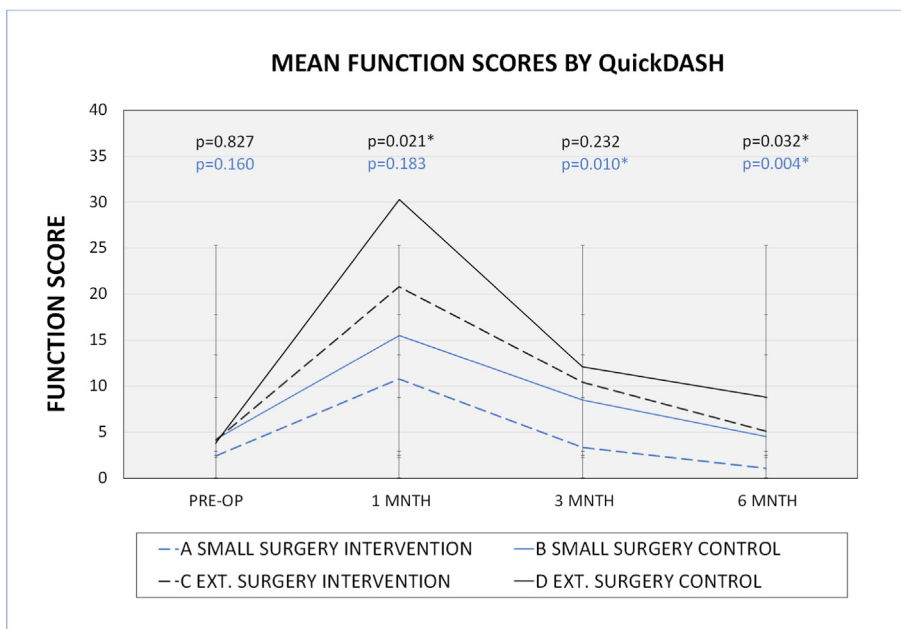


Fig. 2. Mean function scores over time in four study groups. Abbreviations: PRE-OP: Preoperative, MNTH: Month.

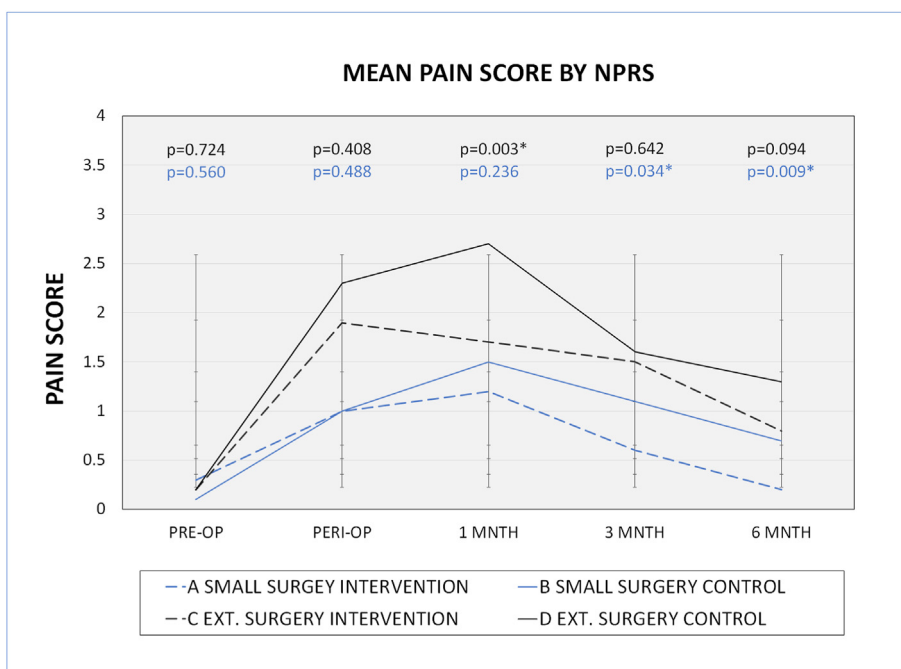


Fig. 3. Mean pain scores over time in the four study groups. Abbreviations: PRE-OP: Preoperative, PERI-OP: Perioperative (during hospitalization), MNTH: Month.

reported with a high incidence of patients [25]. As was demonstrated before, the results show that postoperative exercises can have a positive effect on pain levels after BC surgery [27,28]. Nonetheless, unlike previous studies, that found that treatment programs that include exercises are effective in reducing pain and improving ROM after breast surgery [29], the intervention did not contribute to improvement in ROM or function. Perhaps, a comprehensive PT rehabilitation programs [30], which begins at the hospital and continues after discharge, will maximize the recovery process [31]. Additionally, we comply with Hack et al. which concluded that comprehensive programs are needed to manage

and rehabilitate the morbidity of the arm in all its range of symptoms and associated psychosocial and functional sequelae [32].

In order to get a more accurate presentation of the effect of the type of surgery, the sample was divided into small and extensive surgeries. And as expected, patients undergoing extensive surgeries reported higher pain and disability levels than patients undergoing conservative surgeries, as found previously [33]. The deviation by the extent of surgery revealed another positive effect of the intervention on function, ROM, and pain, although not throughout the follow-up period, and therefore an unequivocal conclusion could not be drawn, especially regarding ROM.

The results show that the early start of PT during hospitalization, did not cause significantly more incidences of seroma [34,35], or bleeding [10,15], and thus can be recommend. While De Groef, in a literature review, found conflicting results regarding the timing of the start of the exercises, he concluded that further research was needed [29]. Cinar et al. previously found that early initiation of the rehabilitation program after radical mastectomy, improved shoulder motility and ability to function, without causing adverse effects in the postoperative period [36].

Lymphedema is a chronic condition that affects the quality of life of women recovering from BC [37], however, due to the small number of participants that have undergone ALND, no conclusions could be drawn regarding the effect of the intervention on lymphedema development. Furthermore, since most often lymphedema develops in the first two years after surgery [38], the incidence of lymphedema development should be assessed by a longer follow-up.

AWS is a transient condition, often develops within weeks following BC surgery and may present as one or more visible or palpable tight cords of tissue in the axilla [39], causing pain and movement limitation [40]. It has previously been found that risk factors for AWS include younger age, the extent of surgery, number of resected lymph nodes, lower body mass index, adjunctive chemotherapy, and radiation therapy [41]. Nevertheless, the effect of postoperative exercises has not yet been examined. Early start of tailored exercises for BC patients and instructions to continue exercising at home did not cause more cases of AWS.

This study has a has several limitations that may lead to a negative impact on the results. The sample size was calculated based on the functional limitations scores of BC patients compared with general population. Since a lot of situations could influence the results, we grouped small and extensive surgeries, considering this study as a pilot study leading basis for future studies. Surgeries were performed by different surgeons, and specific difference of the techniques were not evaluated, only the different type of surgeries, however differences were not observed between groups. Although lymphedema and AWS was self-reported, patients had the opportunity to telephone to the physical therapist and to be clinically evaluated. In addition, adherence to the protocol was not evaluated therefore possible vies and limitations could affect the results.

We believe that PT should begin at hospitalization and be extended in the postoperative period according to the patients' needs and complains. Since, although not observed at all times and outcome measures, better results were obtained in the intervention group.

5. Conclusion

PT that includes exercises and patient education from the first day after BC surgery, do not affect the incidence of postoperative complications, and contributes to pain reduction. When the extent of the surgery was assessed, better results were observed in the group receiving PT, both in pain levels and functional disability scores, with less impact on shoulder flexion and abduction ROM. However, in order to achieve unequivocal results this should be examined in a larger study.

Author contributions

Ifat Klein: ROLES Conceptualization, Methodology, Supervision, Writing – original draft, Data curation, Formal analysis, Project Administration, Investigation, Writing – review & editing. Leonid Kalichman: ROLES Conceptualization, Methodology, Supervision, Visualization, Writing – original draft, Writing – Review & Editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.breast.2021.07.013>.

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